Claims Amendments

The claims have been amended to delete reference to the term "emulsan analog." The term "emulsan" is defined in the specification at, for example, page 9, lines 10-12:

> "Emulsan" as defined herein, are groups of polyanionic amphiphathic lipoheteropolyaccharides secreted by *Acinetobacter calcoaceticus* RAG-1 when fed ethanol.

"Emulsans" embrace polyanionic amphiphathic lipoheteropolyaccharides secreted by mutants of *A. calcoaceticus* (e.g., transposon mutants) or from bacteria other than *A. calcoaceticus*. As stated at page 9, line 21 through page 10, line 7:

> As used herein, the term "emulsan analog" also refers to emulsans obtained from *A. calcoaceticus* mutants (e.g., transposon mutants) which can be, for example, emulsans obtained by mutants grown on ethanol as well as mutants grown on carbon sources other than ethanol (e.g., ethyl propionate). Emulsan and emulsan analogs obtained from *Acinetobacter S.* ATCC 31012 or from mutants thereof are described for example in US 4,311,829, the teachings of which are incorporated herein by reference in their entirety.
>
> In a preferred embodiment of the invention, emulsan and emulsan analogs are obtained from *A. calcoaceticus* strain RAG-1 or from transposon mutants of *A. calcoaceticus* RAG-1. Emulsan and emulsan analogs can be obtained from Acinetobacter Sp. ATTC (American Type Culture Collection) 31012 and mutants thereof as described in U.S. patent No. 4,311,829 by Gutnick *et al.* (1982), the teachings of which are incorporated herein by reference in their entirety. Additionally, or alternatively, emulsan analog also includes emulsans having structures such as shown in Figure 1 which might be obtained from bacteria other than *A. calcoaceticus*. Emulsan or emulsan analogs also can be synthesized chemically in the absence of a bacterial cell and used in the immunization formulations described herein.

The claims have also been amended to specify that the emulsan component is an adjuvant. Support for this amendment to the claims can be found in the specification, for example, at page 6, line 12 through page 7, line 8.

Claim 4 and Claims 14 through 37 have been cancelled. No new matter has been added.

Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

Claims 1-13 and 38 remain rejected under 35 U.S.C. § 112, second paragraph, as being rendered vague and indefinite by use of the term "analog."

As discussed with the Examiner in a telephone interview conducted April 29, 2003, Applicants have amended the claims to remove reference to the term "emulsan analog." As amended, the claims particularly point out and distinctly claim the subject matter which Applicants regard as their invention and, therefore, meet the requirements of 35 U.S.C. § 112, second paragraph.

Rejection of Claims Under 35 U.S.C. § 102(b)

Claims 1-11 and 37-38 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Gutnick *et al.* (U.S. Patent 4,311,829). In particular, the Examiner stated that, although the references failed to show certain features of Applicants' invention, features upon which the Applicants relied in a Reply filed February 19, 2002 (i.e., wherein the emulsan generates a minor immune response in comparison to the antigen), are not recited in the claims. Further, the Examiner stated that, although the claims are to be interpreted in light of the specification, limitations from the specification are not to be read into the claims.

Applicants have amended the claims to make explicit the limitation that the emulsan component of the immunization formulation of the methods of use of such an emulsan formulation are adjuvant components. More specifically, the adjuvant component identified in claims directed to immunization formulations is now identified to be an "emulsan adjuvant."

As discussed with the Examiner in the telephone interview conducted on April 29, 2003, there is no disclosure or suggestion in Gutnick *et al.* of employing an immunization formulation wherein the emulsan component is an adjuvant. Therefore, Gutnick *et al.* do not disclose or suggest Applicants' claimed immunization formulation. Claims 1-13, 37 and 38 meet the requirements of 35 U.S.C. § 102(b) in view of Gutnick *et al.*

Rejections of Claims Under 35 U.S.C. § 103(a)

Claims 1 and 12 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Gutnick *et al.* in view of Fino (U.S. Patent 5,464,746). In particular, the Examiner stated that, as with the rejection of claims under 35 U.S.C. § 102(b), features upon which the Applicants rely (i.e., the emulsan, generates a minor immune response in comparison to the antigen) are not recited in the claims.

As discussed above, Claims 1 and 12 have been amended to make clear that the emulsan component of the claimed immunization formulation is an adjuvant component of the formulation.

As with Gutnick *et al.*, there is no disclosure or suggestion in Fino of an immunization formulation that includes an antigen and an emulsan adjuvant. Therefore, neither Gutnick *et al.* nor Fino, taken either separately or in combination, disclose or suggest Applicants' invention as now claimed.

Claims 1 and 12 meet the requirements of 35 U.S.C. § 103(a).

Objection to Claim 13

The Examiner stated that Claim 13 is free of the art of record, but is objected to as being dependent upon rejected claims.

Claim 13 is dependent from Claim 12, which, in turn, is dependant from independent Claim 1. As discussed above, Claim 1 has been amended to include the limitation that the emulsan component is an emulsan adjuvant. As amended, Claim 1 meets the requirements of 35 U.S.C. §§ 112, 102(b) and 103(a). Therefore, the basis for rejection of Claim 13 has been obviated.

## SUMMARY AND CONCLUSIONS

Claims 1-3, 5-11 and 38 have been amended, as necessary, to delete reference to the term "emlsan analog." These claims also have been amended to make explicit that the emulsan component of the claimed immunization formulation is an emulsan adjuvant. As amended, the

pending claims meet the requirements of 35 U.S.C. §§ 112, second paragraph, 102(b) and 103(a), thereby obviating the outstanding rejections.

If the Examiner believes that a telephone conference would expedite prosecution of this application, he is invited to call the Applicants' undersigned attorney at (978) 341-0036.

Respectfully submitted,
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Dated: 5/29/03

MARKED UP VERSION OF AMENDMENTS

Specification Amendments Under 37 C.F.R. § 1.121(b)(1)(iii)

Please amend the title at page 1, lines 1-2 and page 47, lines 1-2 as follows:

EMULSAN [AND EMULSAN ANALOGS] ADJUVANT IMMUNIZATION FORMULATIONS AND USE

Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

1. (Amended) An immunization formulation, comprising:
   a) an antigen; and
   b) an emulsan [or emulsan analog] adjuvant.

2. (Amended) The immunization formulation of Claim 1, wherein the emulsan [or emulsan analog] adjuvant is secreted from *Acinetobacter calcoaceticus*.

3. (Amended) The immunization formulation of Claim 2, wherein the emulsan [or emulsan analog] adjuvant is secreted from *Acinetobacter calcoaceticus* RAG-1.

5. (Amended) The immunization formulation of Claim [4] 1, wherein the emulsan [analog] adjuvant is secreted by a mutant of *Acinetobacter calcoaceticus*.

6. (Amended) The immunization formulation of Claim 5, wherein the emulsan [analog] adjuvant is secreted by a transposon mutant of *Acinetobacter calcoaceticus*.

7. (Amended) The immunization formulation of Claim [4] 1, wherein the emulsan [analog] adjuvant has an average fatty acid chain length in a range of between about 10 carbons and about 20 carbons.

8. (Amended) The immunization formulation of Claim [4] 1, wherein the emulsan [analog] adjuvant has a fatty acid density in a range of between about 25 nmol/mg emulsan and about 900 nmol/mg emulsan.

9. (Amended) The immunization formulation of Claim [4] 1, wherein the emulsan [analog] adjuvant has an amount of saturated bonds in fatty acids of the analog in a range of between about 80 mole % and about 100 mole %.

10. (Amended) The immunization formulation of Claim [4] 1, wherein the emulsan [analog] adjuvant has an amount of hydroxylated fatty acids in a range of up to 65 mole %.

11. (Amended) The immunization formulation of Claim [4] 1, wherein the emulsan [analog] adjuvant is formed by feeding *Acinetobacter calcoaceticus* or a mutant thereof a compound selected from the group consisting of fatty acids, fatty acid salts, hydroxylated fatty acid salts and complex carbon sources that include fatty acids, said group having a carbon chain length in a range of between about 10 carbons and about 20 carbons.

38. (Amended) A formulation comprising an antigen and an emulsan [analog] adjuvant for stimulating an immune response in an organism.